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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/848,798 | 05/04/2001 | Donald L. Siegel | 9596-42U3<br>(053893-5008-02 | 9049 |

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MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

| EXAMINER |
|---|
| CELSA, BENNETT M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

DATE MAILED: 09/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/848,798 | Siegel |
| **Examiner** | **Art Unit** |
| Bennett Celsa | 1639 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *11-14 and 22-37* is/are pending in the application.

4a) Of the above, claim(s) *14, 22-24, 27-32, and 35-37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11-13, 25, 26, 33, and 34* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

### *Status of the Claims*

Claims 11-14 and ~~23~~ 22-37 are currently pending.

Claims 14, 22-24, 27-32 and 35-37 are withdrawn as directed to a nonelected invention.

Claims 11-13, 25, 26 and 33-34 are under consideration to the extent they read on the elected invention.

### *Election/Restriction*

1. Applicant's election without traverse of Group I (claims 11-13 and 22-37) in Paper No.5 is acknowledged.

2. Applicant's further election, with traverse , in Paper No. 5 of nucleic acid seq 97 (which encodes a protein of seq. Id 28) which reads on claims 11-13, 25, 26 and 33-34 is acknowledged. Applicant argues that it is not an undue search burden to search nucleotide sequences of SEQ ID No's 70-138 and 182-224 together since the nucleotide sequences of SEQ ID No's 70-138 and 182-224 are sufficiently similar such that a search of any one of these sequences would necessarily uncover art for the other. Applicant further argues that the remaining nucleotide species be searched if Seq. Id. No. 97 is found allowable.

Applicant's arguments were considered but deemed nonpersuasive for the reasons provided in the restriction/election requirement See. MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical

compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. *The examination of more than one sequence would now pose an undue burden on the Office.*

Accordingly, the above restriction/election requirement is hereby maintained.

3. Claims 14, 22-24, 27-32 and 35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13, 25, 26 and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 11 (and claims dependent thereon), the use of a successive series of open-ended language: e.g. "having" followed by "comprising", renders the meaning of the claim vague or indefinite and the metes and bounds of claim coverage uncertain. Amending to delete "having an amino acid sequence" will overcome this rejection.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 11-13, 25, 26 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (Lack of Written Description) .

In this regard, applicant is referred to the case of *University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and the "Guidelines for Examination of Patent Applications Under the 35 USC 112, first paragraph, 'Written Description' Requirement" published in 1242 OG 168-178 (January 30, 2001).

The present claims encompass "isolated DNA (e.g. seq. Id 97) encoding" a protein "comprising" a protein (e.g. seq. ID #28 a 131 amino acid protein).

*Accordingly, the presently claimed invention includes:*

*The specific human c-DNA of elected seq. Id. 97 and its encoded human protein of seq. Id #28 along with .*

*I. Additional undefined genetic structure encoding additional amino acids to the C- and/or N-terminus region of the protein of seq. Id #28;*

*II. Additional undefined genetic structure to* include continuous or discontinuous regions encoding the protein of seq. Id # 28 which encompasses the "gene" and those coding or non-coding sequences; and

III. Non-human genetic structure corresponding to I and II above. .

The specification disclosure of a single isolated human cDNA (seq. Id. 97) that encodes a single human anti-Rh(D) protein (seq. Id. 131) fails to meet the written description requirement.

The written description provision of 35 USC 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.)

Applicants have not described nor disclosed the "operon" which encodes a gene which encodes human anti-Rh(D) protein (seq. Id. 131). A gene is broadly defined in the art as a segment of DNA involved in the production of a polypeptide and which includes regions preceding and following the coding regions (i.e. leader and trailer) as well as regions in between individual coding segments. The specification fails to describe the functional gene *per se* (i.e., operon) which applicants have intended to be encompassed by the comprising and encoding language of the instant claims as set forth *supra.*

Moreover, the claims encompass open reading frames which are 3' and 5' to the polynucleotide sequence of SEQ ID NO:97 and similarly encoding the amino acid sequence of SEQ ID NO: 28, such 5' and 3' information inclusive of the definition of an operon. These

regulatory and other gene sequences of the operon that are not described, are essential to the function of the gene within the operon and are therefore essential elements. Such sequences fail to have an adequate written description in the instant specification. The specification does not provide written description support for any flanking nucleic acid sequences which are 5' or 3' of SEQ ID NO:97 or that gene which encodes SEQ ID NO:28. Since, applicants have not disclosed any information which is 3' and 5' to the polynucleotide sequence of SEQ ID NO:97 and therefore clearly lacks written description for the broad class of polynucleotides comprising SEQ ID NO:97. Thus, the written description of the instant specification does not provide for "comprising" language with respect to SEQ ID NO:97. In the instant case, the specification provides only written description for a polynucleotide consisting of SEQ ID NO:97 which encodes the protein of seq. Id. 28.

The actual structure or other relevant identifying characteristics of each nucleic acid that encodes a protein having the disclosed properties (e.g. anti-Rh(D) protein ) can only be determined empirically by actually making every nucleic acid that encodes the recited protein and testing each to determine whether it encodes a protein having the particularly disclosed properties. As noted in the Guidelines at Section IIA(2):

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention from its function.

Function can not be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of an anti-Rh(D) protein as disclosed. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number anti-Rh(D) proteins, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide consisting of SEQ ID NO:97 and an isolated anti-Rh(D) protein of seq. 28, the skilled artisan cannot envision all the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Additionally, to the extent that the presently claimed invention encompasses non-human as well as human genetic sequences that encode proteins comprising amino acid sequences, Applicants' attention is directed to The Court of Appeals for the Federal

Circuit which held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). (bracketed material in original)[The claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA (encoding insulin)]. More specifically, the *Eli Lilly* court held that the demonstration of a single cDNA species constituted inadequate written support for a generic of mammalian species due to genetic variation among species and the lack of sufficient core structure. A similar result is warranted in the present case.

Therefore, only an isolated polynucleotide consisting of SEQ ID NO: 97 encoding SEQ ID NO:28, but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.) Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

**General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang (art unit 1639), can be reached at (703)306-3217.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1639)

September 29, 2003

BENNETT CELSA
PRIMARY EXAMINER